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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,490	03/12/2004	Karl Bruce Thor	046562/274661	8365

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EXAMINER	
HUYNH, CARLIC K	
ART UNIT	**PAPER NUMBER**
1617	

MAIL DATE	DELIVERY MODE
07/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/799,490	THOR, KARL BRUCE	
	Examiner	Art Unit	
	Carlic K. Huynh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) *11,12 and 22-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 13-21* is/are rejected.

7)☒ Claim(s) *1* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :30 August 2004 and 22 November 2004.

DETAILED ACTION

Status of the Claims

Claims 1-43 are pending in the application, with claims 22-43 having been withdrawn from consideration, in response to the restriction requirement submitted on January 4, 2007. Accordingly, claims 1-21 are being examined on the merits herein.

Election/Restrictions

1. Applicant's election with traverse of the claims of Group I, namely claims 1-21, in the reply filed on May 17, 2007 is acknowledged. Because Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 22-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made with traverse in the reply filed on May 17, 2007. Because Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Applicant's election with traverse of the species of (1) the active agent corresponding to the compound of claim 1(a) in the reply filed on May 17, 2007 is acknowledged. The traversal is on the ground(s) that the compound of claim 1(b) is encompassed by claim 1(a) thus the species of 1(a) and 1(b) should be examined together.

Applicants' arguments were found persuasive in part. The examiner maintains and argues that there is a search burden for the compounds other than those compounds corresponding to claim 1(a) and 1(b), namely compounds 1(c) through 1 (ss). The different compounds corresponding to claim 1(c) through 1(ss) would render each compound of claim 1 other than 1(a) and 1(b) to be of a different design and thus a search burden has been established between compounds of 1(c) through 1(ss).

3. Applicant's election without traverse of the species of (2) the second listed compound of claim 20 as the additional active agent; (3) oral administration as the mode of administration; and (4) unit dosage form corresponding to claim 7 as the dosage form in the reply filed on May 17, 2007 is acknowledged.

The election of species requirement of (2) the second listed compound of claim 20 as a species of the additional active agent has been withdrawn.

Claims 1-21 are read to draw on the elected species of a compound of claim 1(a), oral administration, and unit dosage form.

Claims 11 and 12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on May 17, 2007.

Accordingly, claims 1-10 and 13-21 are being examined on the merits herein.

The restriction requirement and the election of species requirement for a compound of formula (I) are still deemed proper and are therefore made FINAL.

Information Disclosure Statement

The Information Disclosure Statements submitted on August 30, 2004 and November 22, 2004 are acknowledged.

Specification

4. The use of the trademark VIAGRA®, Sentry Polyox®, Gantrez®, Methocel®, Klucel®, Polyplasdone®, Ac-di-sol®, Explotab®, Di-Tab®, Di-Pak®, Azone®, SEPA®, Tergitol®, Nonoxynol-9®, TWEEN-80®, SynchroMed®, Atrigel®, Eligard®, Atridox/Doxirobe®, Atrisorb®, FreeFlow™, BEMA™, SMPT™, MCA®, BCP™, and Orajel® has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Claim Objections

5. Claim 1 is objected to because of the following informalities: informal language. In claim 1, parts a, c-f, h-mm, oo-pp, and rr, the phrase "(illustrated below) as disclosed in" is considered informal. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-10 and 13-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poss et al. (US 6,225,324) in view of Childers et al. (US 6,469,007).

Poss et al. teach a method of inhibiting re-uptake of endogenous serotonin that is also effective in the treatment of depression comprising the oral administration of compounds of formula (I) (column 3, lines 1-8; column 12, lines 30-34; and column 13, line 7). Poss et al. also teach the compounds used for treating depression may be administered individually or as mixtures with other therapeutic agents (column 13, lines 17-19). Furthermore, Poss et al. teach dosage forms of tablets and caplets (column 13, line 26).

Poss et al. do not specifically teach a method of treating sexual dysfunction, when to administer the active agent, controlled or delayed dosage forms, and effervescent tablets.

Childers et al. teach piperazine derivatives used for the treatment of depression such as by the potentiation of serotonin reuptake inhibitors and sexual dysfunction (abstract and column 7, lines 4-6 and 12). Childers et al. also teach administration of the piperazine derivatives 0.5, 2, and 4 hours prior to administration of the 5-HT_{1A} agonist 8-OH-DPAT (column 6, lines 30-21 and Table 4).

To a person of skill in the art at the time of the invention, it would have been obvious to employ the antidepressant agent of formula I of Poss et al. to be used in a method for treating sexual dysfunction because the piperazine derivatives of Childers et al. are piperazine derivatives used to treat depression and according to Childers et al., the piperazine derivatives used to treat depression can also be used to treat sexual dysfunction.

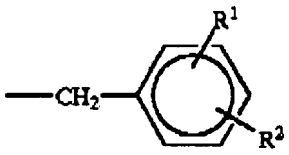
The motivation to combine the composition of Poss et al. to the compounds of Childers et al. is that the compounds of Childers et al. are antidepressants that are also useful as a treatment for sexual dysfunction.

Regarding controlled release dosage form as recited in instant claim 8, Childers et al. teach tablet-disintegrating agents, which meets the limitations of the instant claims (column 7, lines 49-50). Childers et al. teach a number of tablet-disintegrating agents that could yield the controlled release dosage form that is recited in instant claim 8. It would obvious that the tablet-disintegrating agents taught by Childers et al. are controlled release dosage forms.

Regarding delayed release dosage form as recited in instant claim 9, Childers et al. teach tablet-disintegrating agents, which meets the limitations of the instant claims (column 7, lines 49-50). Childers et al. teach a number of tablet-disintegrating agents that could yield the delayed release dosage form that is recited in instant claim 9. It would obvious that the tablet-disintegrating agents taught by Childers et al. are delayed release dosage forms.

Regarding effervescent tablet as recited in instant claim 16, Childers et al. teach tablet-disintegrating agents, which meets the limitations of the instant claims (column 7, lines 49-50). Childers et al. teach a number of tablet-disintegrating agents that could yield the rapidly disintegrating effervescent tablet that is recited in instant claim 16. It would obvious that the tablet-disintegrating agents taught by Childers et al. are effervescent tablets.

Regarding the active agent as recited in instant claim 21, Poss et al. teach a compound of formula I, which meets the limitation of the compound in the instant claim 21 (column 3, lines 1-8 and 20-28). The compound in instant claim 21 is the compound in 1(a) where Z is a phenyl substituted with 2 alkoxy, namely methoxy, groups and Y is:



, where R_1 is hydrogen and R_2 is a halogen, namely bromine.

Conclusion

7. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlic K. Huynh whose telephone number is 571-272-5574. The examiner can normally be reached on Monday to Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SHENGJUN WANG
PRIMARY EXAMINER

ckh